MAY 1 8 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Carbamazepine Method for ADVIA IMS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K000903 (leave blank)

1. **Intended Use**

This in vitro method is intended to quantitatively measure carbamazepine in human serum on the Bayer ADVIA IMS systems. Measurements of carbamazepine are used to aid in attaining optimum therapy in patients treated with the drug.

2. **Predicate Device**

Product Name	Reagent Part #	Calibrator Part #
Abbott TDx Carbamazepine	9515-60	9515-01

3. **Device / Method**

Product Name	Reagent BAN	Calibrator BAN
ADVIA IMS Carbamazepine	00977063	05347112

A. Imprecision

ADVIA IMS	
Level (µg/mL)	Total CV (%)
3.7	5.1
7.3	3.0
10.8	2.8

Abbot TDx	
Level (µg/mL)	Total CV(%)
3.0	6.9
6.0	3.5
16.0	2.9

B. Correlation (Y=ADVIA IMS, X=Comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (ng/mL)	R	Sample Range (ng/mL)
Serum	TDx	52	Y=0.99X - 0.35	0.53	0.987	1.9 – 17.0

C. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Carbamazepine Conc. (µg/mL)	Effect (% change)
Bilirubin (unconjugated)	25	9.6	8.6
Bilirubin (conjugated)	25	10.2	3.5
Hemoglobin	1000	10.3	1.4
Lipids (Triglycerides)	1000	10.1	-3.9

Analytical Range: 0.3-20.0 µg/mL

Date _____

Bayer Corporation, Business Group Diagnostics
Tarrytown, NY.

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs

914-524-3494 (fax 914-524-2500)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Quinidine Method for ADVIA IMS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K000903 (leave blank)

1. Intended Use

This in vitro method is intended to quantitatively measure quinidine in human serum on the Bayer ADVIA IMS systems. Measurements of quinidine are used to aid in attaining optimum therapy in patients treated with the drug.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Abbott TDx Quinidine	9506-20	9506-01

3. Device / Method

Product Name	Reagent BAN	Calibrator BAN
ADVIA IMS Quinidine	02346565 (100 test) 01531679 (250 test)	06053872

A. Imprecision

ADVIA IMS	
Level (µg/mL)	Total CV (%)
1.9	3.2
2.7	4.8
6.1	3.6

Abbot TDx	
Level (µg/mL)	Total CV(%)
1.5	3.9
3.0	3.5
6.0	3.5

B. Correlation (Y=ADVIA IMS, X=Comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (µg/mL)	R	Sample Range (µg/mL)
Serum	TDx	50	Y=0.87X + 0.03	0.21	0.991	0.1-6.6

C. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Quinidine Conc. (µg/mL)	Effect (% change)
Bilirubin (unconjugated)	25	3.4	-7
Bilirubin (conjugated)	25	3.1	+1
Hemoglobin	500	3.5	-4
Lipids (Triglycerides)	1000	3.4	+6

Analytical Range: 0.02-8.0 µg/mL

Date _____

Bayer Corporation, Business Group Diagnostics
Tarrytown, NY.

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs

914-524-3494 (fax 914-524-2500)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 8 2000

Mr. Fredrick Clerie
Director Regulatory Affairs
Bayer Corporation
Business Group Diagnostics
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K000903
Trade Name: ADVIA IMS Carbamazepine Assay
ADVIA IMS Quinidine Assay
Regulatory Class: II
Product Code: KLT, LBZ
Dated: March 15, 2000
Received: March 21, 2000

Dear Mr. Clerie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000903

Device Name: **ADVIA IMS Carbamazepine Assay**

Indications For Use:

This *in vitro* diagnostic procedure is intended to quantitatively measure carbamazepine, an anticonvulsant drug, in human serum or plasma (lithium heparin) using EMIT* (Enzyme Multiplied Immunoassay Technique) 2000 technology on the BAYER ADVIA® Integrated Modular System (Bayer ADVIA® IMS™) system. Measurements of carbamazepine are used in monitoring serum or plasma levels of carbamazepine to ensure appropriate therapy and in the treatment of carbamazepine overdose.

This diagnostic method is not intended for use on any other system.

Device Name: **ADVIA IMS Quinidine Assay**

Indications For Use:

This *in vitro* diagnostic procedure is intended to quantitatively measure quinidine, an antiarrhythmic drug, in human serum or plasma (lithium heparin) using EMIT* (Enzyme Multiplied Immunoassay Technique) 2000 technology on the BAYER ADVIA® Integrated Modular System (Bayer ADVIA® IMS™) system. Measurements of quinidine are used in the diagnosis and treatment of quinidine overdose and in monitoring serum levels of quinidine to ensure appropriate therapy.

This diagnostic method is not intended for use on any other system.

(Division Sign-Off)
Division of
510(k) Number K000903

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)